UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF RICHARD WENZEL, M.D.

TABLE OF CONTENTS

INTRODUCTION

This Court should deny Plaintiffs' motion to exclude the expert opinions of internist and epidemiologist Dr. Richard P. Wenzel because Plaintiffs' motion is based on a gross oversimplification of Dr. Wenzel's analysis. Dr. Wenzel combines extensive professional experience with a review of decades of scientific literature across interrelated subject matters in support of his opinions that (1) *the Bair Hugger system is not generally capable of causing a prosthetic joint infection*; and (2) the most likely cause is the bacteria on and in the patient's own body. Dr. Wenzel's opinions are admissible because they are both reliable and relevant. They will assist the trier of fact in deciding the central causation issue in this case.

Dr. Wenzel is abundantly qualified to offer his opinions. He has in-depth experience in clinical medicine and infectious diseases, and has been directly involved in the care of hundreds of patients with prosthetic joint infections (PJIs). He is also supremely qualified to interpret and critique scientific literature based on his vast experience as a researcher and editor. Notably, Dr. Wenzel has over 500 published manuscripts and is the editor of numerous textbooks and journals addressing infection control and infectious diseases.

Drawing on his expertise as an infectious disease epidemiologist, Dr. Wenzel explains that in a case like this where (i) a surgical site infection is not part of a cluster (i.e., an outbreak of infections above the normal background rate, often linked to a specific marker organism or mode of transmission), (ii) the bacterium implicated is commonly found on and in the patient's own body (the microbiome), and (iii) the

investigation is not close in time to the date of the surgery, there is no scientifically valid method for identifying the source of any particular patient's infection retrospectively. Because this is the starting point for investigating causation here, Dr. Wenzel analyzes scientific literature across numerous subjects to aid the trier of fact in understanding both what is capable of causing the Plaintiffs' infections and what likely caused them. *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 412 (S.D.N.Y. 2016) ("a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable").

Dr. Wenzel considered the body of evidence on forced-air warming, specifically the Bair Hugger system, and concludes there is no valid scientific evidence to establish that the Bair Hugger system is capable of causing a PJI. The evidence establishes, instead, that use of the Bair Hugger system is both safe and a widely accepted infection-control strategy. Dr. Wenzel also concludes the bacteria on and in a patient's own body are the most likely cause, and a cause that cannot be ruled out. This Court should admit Dr. Wenzel's testimony because it will assist the trier of fact in understanding the scientific literature related to surgical site infections, including what is known and knowable about the likely cause of infection for any particular patient.

I. DR. WENZEL'S QUALIFICATIONS, METHODOLOGY, AND OPINIONS.

A. Dr. Wenzel Is Well-Qualified to Render His Opinions.

Dr. Wenzel is a Board Certified Infectious Disease Specialist and Board Certified Internist. DX1[1], *Curriculum Vitae* for Dr. Richard P. Wenzel, attached as Exhibit A to Expert Report of Dr. Richard P. Wenzel ("Wenzel Report"). He holds a Doctor of Medicine from Jefferson Medical College (1965) and a Master of Science in Epidemiology from the University of London, London School of Hygiene and Tropical Medicine (1986). He is Former Chairman of the Department of Internal Medicine at the Virginia Commonwealth University School of Medicine, where he is Professor Emeritus. *Id.* at 4. Dr. Wenzel has treated hundreds of patients with PJIs since earning his Doctor of Medicine in 1965.

In addition to providing direct patient care, Dr. Wenzel has devoted a significant part of his professional life to understanding infectious diseases, and specifically, infection control in hospitals. He is a former President of the International Society for Infectious Diseases and former President of the Society of Healthcare Epidemiologists of America. He has worked with national and international organizations to address issues related to understanding and controlling infectious diseases, including: the Centers for Disease Control and Prevention (including work related to healthcare infection control); the National Institutes of Health (including as a member of the Microbiology and Infectious Diseases Research Committee from 1997-2000); and the World Health

[1] Cites to "DX" are exhibits to the Declaration of Mary S. Young filed concurrently with this opposition.

Organization (WHO Expert Advisory Panel, Acute Bacterial Diseases, 1984 – present). *Id.* at 5-8.

Dr. Wenzel's career is also marked with significant publishing and editing experience. He is the editor of seven textbooks on infection control and infectious disease. He is the founding editor of two journals, *Infection Control and Hospital Epidemiology* and *Clinical Performance and Quality Health Care*, and he has served on journal editorial boards of nearly a dozen other journals. He has held the position of Editor-at-Large for the prestigious *New England Journal of Medicine* since 2001.

Dr. Wenzel is undoubtedly qualified based on his training, experience, and education, to examine the scientific literature across all of the topics included in his report, which culminate in his causation opinions. Where microbiology, laminar flow, and hypothermia interface with infectious diseases, Dr. Wenzel has the requisite expertise as well. DX2, Deposition of Richard P. Wenzel, M.D., MSc., taken Aug. 4, 2017 ("Wenzel Depo.") at 31:15-32:5; 142:25-143:10; 143:25-144:20.

B. Dr. Wenzel's Opinions and Methodology.

Dr. Wenzel's opinion that the Bair Hugger patient warming system is not generally capable of causing a PJI is at the heart of this case. He concludes there is no valid scientific support for Plaintiffs' claim that use of the Bair Hugger system causes harm. Rather, warming patients during surgery using the Bair Hugger system is a widely accepted infection-control strategy and proven safe for patients – like Plaintiffs – who have undergone total knee or total hip replacements. *See* DX1, Wenzel Report at 74. Dr. Wenzel also offers opinions to assist the trier of fact in answering additional causation-

related questions: "*If the Bair Hugger is not generally capable of causing PJIs, what is the likely cause of the Plaintiffs' PJIs and how do we know that?*"

To answer these questions, Dr. Wenzel drew upon his own expertise and his analyses of voluminous scientific research and literature across the following interrelated topics: the adverse effects associated with hypothermia in patients undergoing anesthesia; the clinical benefits of patient warming using the Bair Hugger system; the role of the microbiome in surgical site infections; whether laminar flow in operating rooms impacts the rates of surgical site infections; and how a patient's risk factors impact surgical site infection rates. DX1, Wenzel Report at 3-58. By analyzing each of these topics, Dr. Wenzel lays the foundation for his ultimate opinions that the patient's own microbiome is the most likely cause of a Plaintiff's PJI. Dr. Wenzel also systematically reviewed the research involving the Bair Hugger system; specifically, research looking at whether use of the Bair Hugger increases bacteria at the surgical site. *Id.* at 58-68. He concludes that the Bair Hugger system is not generally capable of causing PJIs. *Id.* at 74.

Dr. Wenzel's report details his in-depth analysis and critique of dozens and dozens of pieces of scientific research. He explains whether and how each piece of research is applicable to understanding the central causation question in this case, and in many instances, he also includes the actual data and specifically addresses its strengths or limitations. *See, e.g.*, Wenzel Report at 30, 32, 38. Dr. Wenzel uses a recognized and reliable framework for evaluating the quality and validity of scientific evidence, described as the "hierarchy in ascribing causal relationships." DX1, Wenzel Report at

17-18.[2] He explains that a meta-analysis of several well conducted, prospective clinical trials that were controlled, randomized, and blinded represents the highest quality scientific evidence; while case reports and expert opinion are at the bottom of the hierarchy. DX1, Wenzel Report at 17. In determining whether he will agree or disagree with conclusions in a peer-reviewed article, Dr. Wenzel explained his detailed processes:

> Well, I could go on for a long time, but I think what I would do is look at the methods section in a very critical way. For example: Did they have a clear hypothesis? Did they have a clear endpoint? If they're counting infections, what was the method of case finding? Was there any validity to the case finding technique? . . . If they say they found it, was it really a case, or was it a mistake? Was it – What kind of study was it really; a prospective, a clinical trial, was it observational trial? If it was observational, were the two things that we're interested in looked at concurrently? I'd want to know a little bit about how they, you know, did some power studies, what Alpha was in the study, and the length of follow-up, of course would all be important things. I'd want to look at what statistics that they used and how they were going to evaluate success or not. And I would hope that they would have not only efficacy, but a safety profile to go along by which you could make a, if you will, risk/benefit compared to an alternative.

DX2, Wenzel Depo. at 318:10-319:6.

In sum, Plaintiffs' accusation that the literature was not evaluated in a consistent, scientifically rigorous manner is belied by both the detail included in Dr. Wenzel's report and his deposition testimony:

---

[2] Dr. Wenzel cites an article by Greenhalgh, T. (DX1 at 18), which summarizes the framework for assessing the methodological quality of published articles (referred to as critical appraisal). This generally accepted methodology, including the "hierarchy of ascribing causal relationships," is detailed in a multi-part Users' guides to the medical literature published in *JAMA*. DX5, Greenhalgh T., *How to read a paper, Getting your bearings (deciding what the paper is about)*, BMJ 1997, 315:243-6 (specifically, nn.7-21, 36.)

> Q. So I understand that you read many articles and did an extensive literature search with respect to formulating your opinions in this case; correct?
>
> A. Yes.
>
> Q. Okay. So when you come to your ultimate opinions, what methodology did you use in doing your review to determine your opinions?
>
> A. What I think I've done is actually take a look at the hierarchy of all the studies that fell into any one group. So I looked separately at clinical trials, I looked at meta-analysis, case-control studies, cohorts, national trends, and then the data on CFUs as a biological plausibility. I have -- There are 15 studies from there. I looked at the particle studies, which I think are really distant surrogate markers of infection. And then together, I would say, as -- as a complete package, I can't find any, you know, convincing link between the Bair Hugger and harm.

DX2, Wenzel Depo. at 314:7-25.[3]

ARGUMENT

Plaintiffs cannot credibly dispute that Dr. Wenzel is qualified to render opinions in this case. He is indisputably a leading pioneer in the field of infectious disease epidemiology. He has taken that expertise and methodically applied it to the facts of this case, as detailed in his 75-page report. Plaintiffs' attack on the relevancy and reliability of Dr. Wenzel's opinions is baseless – it is littered with mischaracterizations of both his opinions and the support he offers for them. Dr. Wenzel's testimony meets the criteria of

[3] Plaintiffs' reliance on the *Kinergy Corp. v. Conveyor Dynamics Corp.* case (2003 WL 26110512 (E.D. Mo.)) is unavailing. *See* Plaintiffs' Memorandum, ECF No. 813 at 12. The *Kinergy* court excluded certain opinions by mechanical engineering expert Dr. Davis Peters. The court found the testimony "fundamentally unsupported," including because Dr. Peters conducted no scientific tests, used no equations and formulas, had no experience in designing, manufacturing or operating the equipment at issue, consulted with no other experts in the field, and reviewed no peer-reviewed literature. *Id.* at *20-27. Dr. Wenzel's methods and conclusions in this case are in no way "similar" to those of Dr. Peters that were excluded by the *Kinergy* court.

Rule 702 and Plaintiffs' motion should be denied. *See* Fed. R. Evid. 702; *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (expert testimony must be relevant, i.e., useful to the fact finder in deciding the ultimate issue; the witness must be qualified; and the proposed evidence must be reliable so that if the finder of fact accepts it as true, it provides assistance the finder of fact requires).

I. DR. WENZEL'S OPINION THAT THE BAIR HUGGER SYSTEM IS NOT GENERALLY CAPABLE OF CAUSING PROSTHETIC JOINT INFECTIONS IS ADMISSIBLE.

A. The Body of Scientific Evidence Establishes There Is No Causal Link Between the Bair Hugger System and Prosthetic Joint Infections.

Dr. Wenzel opines that the Bair Hugger system is not generally capable of causing a prosthetic joint infection.[4] Further, Dr. Wenzel concludes that the Bair Hugger is safe, and effective at reducing surgical site infections. Dr. Wenzel systematically reviewed the available scientific literature, including both published research and research that was never published (the "secret studies"[5]), to reach his conclusion. As detailed above, the

[4] Plaintiffs incorrectly state that "Dr. Wenzel does not necessarily opine that the Bair Hugger device does not cause periprosthetic joint infections; instead, his opinion is that there is insufficient evidence to conclude that *airborne bacteria* are the cause of periprosthetic joint infections." Plaintiffs' Memorandum of Law in Support of Motion to Exclude the Testimony and Report of Dr. Richard P. Wenzel, ECF No. 813 at 9. This is a mischaracterization of Dr. Wenzel's opinion, which squarely addresses the Bair Hugger system and affirmatively concludes that the Bair Hugger is *not* capable of causing PJIs.

[5] During discovery in this litigation, it came to light that authors of the eight studies upon which plaintiffs rely (all of which were hypothesis-generated studies that did not measure infection rates or establish any causal link between the Bair Hugger and infections) also attempted, on seven separate occasions, to capture viable bacteria coming out of the Bair Hugger. DX1, Wenzel Report at 60-62. None of the studies showed bacteria being emitted from the Bair Hugger or any increase in bacteria in the operating room or near the operative site. The bacterial counts data was never published and, hence, has been

methodology Dr. Wenzel applied is reliable and accepted in the scientific community. *In re Mirena*, 169 F. Supp. 3d at 412.

To arrive at his opinion about the Bair Hugger, Dr. Wenzel reviewed a "large volume of data" that suggests that an airborne route of bacteria to the wound is not important. DX1, Wenzel Report at 42. Even assuming airborne transmission were important, the question is not – as Plaintiffs suggest – whether use of the Bair Hugger increases particles at the surgical site, but rather whether it increases bacteria. Mark Albrecht, an author of many of the studies upon which Plaintiffs rely, clarified at his deposition that the airborne particles counted do not reflect bacterial counts. DX3, Deposition of Mark Albrecht taken Oct. 7, 2016, at 66:16-19. What could only potentially matter here is whether use of the Bair Hugger system increases bacterial counts in the operating room and at the surgical site. Dr. Wenzel reviewed the literature on the Bair Hugger and concluded that "no study has shown bacterial contamination in the air" from the Bair Hugger blanket when the system is properly used for surgery. DX1, Wenzel Report at 59. In fact, a recent study by Oguz and colleagues in clean orthopedic surgery comparing the Bair Hugger to the Hot Dog warming device (non-forced air warming) found that ***warming with either device had no influence on bacterial counts at any sampling site***. *Id.* at 39-40 (emphasis added).

Dr. Wenzel also reviewed the seven "secret studies," which confirmed that viable bacteria do not come out of the Bair Hugger system, nor does use of the system add to the

---

coined the "secret studies."

bacterial load at the surgical site. DX1, Wenzel Report at 61-62. Based on his review of all of the available data, including deposition testimony of authors of the studies upon which Plaintiffs rely, Dr. Wenzel states:

> One is forced to conclude that a large volume of data has shown that the use of the Bair Hugger has no influence on bacterial counts in the operating room. The authors of these studies failed to publish the data and instead appeared to focus on air currents and particles as implied surrogate markers of bacteria counts.

DX1, Wenzel Report at 62.

In forming his Bair Hugger-specific opinion, Dr. Wenzel also considered the McGovern study (*J. Bone Joint Surgery (BR)* 2011; 93: 1537-44) relied upon by Plaintiffs. DX1, Wenzel Report at 62-68. Of course, the authors of McGovern expressly acknowledge that a causal relationship has not been shown. But after careful dissection of the paper, Dr. Wenzel further concluded the study "should be entirely discounted because of so many failures: it did not correct for numerous confounders, was laced with several biases, and failed to establish a clear definition of case finding and show independent validity of case finding methods to their recorded infection rates." DX1, Wenzel Report at 68, 62-68 (detailing analysis of McGovern).

Based upon his methodical review of the relevant scientific literature, Dr. Wenzel concludes the Bair Hugger system is not generally capable of causing a prosthetic joint infection, and the system is safe and effective at reducing surgical site infections. Dr. Wenzel's conclusions are consistent with all respected independent authorities who have looked at this issue and concluded that the evidence does not show that the use of forced

air warming increases the risk of surgical site infections.[6] Most recently, after collecting and analyzing available data, the FDA issued a "Dear Health Care Provider" letter recommending the continued use of thermoregulating devices, including forced air warming devices, for surgical procedures when clinically warranted. *See* DX1, Supplemental Report of Dr. Richard P. Wenzel and the FDA's August 30, 2017, "Dear Health Care Provider" attached thereto.

B. Plaintiffs' Ad Hoc Attacks on Dr. Wenzel's Bair Hugger-Specific Opinion Should be Rejected.

Airborne bacteria. Dr. Wenzel properly reviewed on-point research to arrive at his opinion that the Bair Hugger system is not generally capable of causing PJIs. Accordingly, Plaintiffs' argument that general statements about airborne bacteria render his opinions unreliable is baseless. Specifically, Plaintiffs argue that Dr. Wenzel's textbook and the International Consensus Statement's discussions of "airborne bacteria" as a potential source of infection render his specific opinions about the Bair Hugger unreliable. This is not the case. Dr. Wenzel's position does not represent a "clear shift of opinion," as Plaintiffs argue. Put simply, whether airborne bacteria in the operating room may correlate to the incidence of PJIs is of no consequence here where study after study proves that the Bair Hugger system *does not* increase bacteria at the surgical site.

[6] *See* Memorandum in Support of Defendants' Motion for Summary Judgment with Respect to General Causation, ECF No. 762 at 21-24 (detailing conclusions of AORN, ECRI, Sikka and Prielipp, the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection, Duke University School of Medicine's Infection Control Outreach Network (DICON), and the FDA).

The Darouiche Study. Dr. Wenzel considered the Darouiche study. He concluded, however, that even if airborne contamination could be linked to implant infections, the study is of no import here because forced air warming using the Bair Hugger *does not increase airborne bacteria counts at the surgical site. In re Mirena*, 169 F. Supp. 3d at 419 (rejecting the Plaintiffs' arguments that Defendants' experts ignored unhelpful research where the criticism was unfounded and the expert had actually addressed the contradictory research). Plaintiffs' argument that Dr. Wenzel's analysis of the Darouiche study shows that he applied an inconsistent methodology is unavailing. Darouiche showed a correlation between numbers of bacteria in the air and the probability of deep surgical site infections. DX1, Wenzel Report at 39. However, what the data in this very small study failed to show was cause and effect; the study left unanswered whether the organism came from the patient's own microbiome or possibly the OR team. Dr. Wenzel considered the Darouiche study and fully addressed why it does not change his opinion. DX1, Wenzel Report at 39; DX2, Wenzel Depo. at 167:4-171:2; 352:2-7.

Misconstrued deposition testimony. Dr. Wenzel applied a rigorous methodology that he thoroughly explains in his report. *See* Section I.B., *supra*. Plaintiffs' attempt to discredit Dr. Wenzel's methodology by misconstruing his deposition testimony also should be rejected. Plaintiffs falsely claim that Dr. Wenzel admitted to extracting favorable data from reports, citing favorable data out of context and using non-contextual data to support his opinions. He testified just the opposite:

> Q. So you like to take – you like to take the data that supports your position –
>
> A. No.
>
> Q. – and then disregard data that doesn't support your position; correct?
>
> A. No, that's not true.

DX2, Wenzel Depo. at 175:18-23. Dr. Wenzel also explained that he addressed studies that had data that did not support his opinions and that although he *disagreed* with authors in certain studies, he did not *disregard* them. *Id.* at 175:21-176:12.[7]

Dr. Wenzel's opinion that the Bair Hugger is not generally capable of causing a surgical site infection, but rather is a safe and effective patient therapy, is scientifically grounded and admissible. Fed. R. Evid. 702.

---

[7] Dr. Wenzel's response to the hypothetical posed at his deposition, which Plaintiffs cite as evidence, somehow, of Dr. Wenzel's lack of reliability is also misquoted in Plaintiffs' Memorandum (ECF No. 813 at 11-12):

> Q. Assuming that with all these studies regarding increased particles, increased bubbles, okay, take into consideration Stocks' particle study and Darouiche's CFU study and periprosthetic joint infections, and assume that periprosthetic joint infections are caused by airborne contamination. Would that affect your opinions in this case of whether or not the Bair Hugger increases periprosthetic joint infection?
>
> A. It's very hypothetical, and as I've told you, probably not *because I would look at the McGovern study as the key clinical study that you're pointing to for the efficacy, or for the – saying what you did about the Bair Hugger.*

DX2, Wenzel Depo. at 350:6-22 (language in italics omitted by Plaintiffs).

II. DR. WENZEL'S OPINION THAT BACTERIA ON AND IN THE PATIENT IS THE MOST LIKELY SOURCE OF A PROSTHETIC JOINT INFECTION IS ADMISSIBLE.

In addition to opining that the Bair Hugger is not generally capable of causing a PJI, Dr. Wenzel provides opinions related, more generally, to the known and most likely cause of the Plaintiffs' PJIs. Dr. Wenzel explains, from an epidemiological standpoint, how to approach the causation question in these cases. Because (i) the surgical site infections are not part of a cluster (i.e., an outbreak of infections above the normal background rate, often linked to a specific marker organism or mode of transmission); (ii) the bacterium implicated is commonly found on and in the patient's own body (the microbiome); and (iii) the investigation is not close in time to the date of the surgery, there is no scientifically valid method for identifying the source of any particular patient's infection retrospectively. DX1, Wenzel Report at 69. Identifying the most likely cause(s) is all that can be done. To this end, Dr. Wenzel analyzed the scientific research addressing numerous aspects of surgical site infections and concluded that the most likely cause of Plaintiffs' infections is the bacteria on and in their own bodies. Plaintiffs' criticism that this opinion is "unreliable because it is not supported by any scientific evidence" could not be further from the truth. Dr. Wenzel's report provides a detailed explanation of the scientific research he relied upon to arrive at this opinion.

First, he explains how every human being has somewhere around a hundred trillion microorganisms living on and in their body – known as the microbiome. DX1, Wenzel Report at 21-22. These bacteria are commonly found on the skin, as well as in the nasal passages, throat, and gastrointestinal tract. *Id.* at 21.

Second, Dr. Wenzel details scientific research showing that patients with certain comorbidities, including diabetes mellitus and obesity, are more frequently carriers of one specific type of microorganism in their nasal passages, *S. aureus* (bacteria responsible for causing PJIs). In turn, nasal carriage of *S. aureus* is linked both to the presence of *S. aureus* on the skin of the patient's hands and also to an increased risk of an *S. aureus* surgical site infections. *Id.* at 23, 32-35.

Third, Dr. Wenzel explains the body of research that establishes reducing the microbiome on the skin at the area of incision incrementally reduces surgical site infections by over 40%. *Id.* at 22-26. Thus, controlling the microbiome, including through antiseptic skin preps and the use of antibacterial creams to "decolonize" the bacteria in the nose, is scientifically proven to reduce surgical site infections. *Id.* at 22-26; 36-37.

Each of these lines of evidence supports Dr. Wenzel's opinion that bacteria that causes PJIs comes from the microbiome of the patient, and Plaintiffs' statement that it is devoid of any scientific evidence is false. In addition, Dr. Wenzel's opinion is wholly consistent with the conclusion reached by the Centers for Disease Control that surgical infections arise from the complex individual circumstances of a patient's surgery and involve, *inter alia*, bacteria that live on patients' skin around the surgical site. DX4, CDC Guideline for Prevention of Surgical Site Infection at 103 (1999).

Dr. Wenzel also explains that while the precise mechanism of travel is unknown, scientific research shows that the bacteria on the patient do, in fact, make their way into the wound – the question that matters here. Researchers have only recently begun to map

the microbiome of the skin by looking at the genes of the bacterial microbiome at specific locations on the body. DX1, Wenzel Report at 27. While *S. aureus* is common to all areas of the skin, the upper back and upper chest are disproportionately colonized with *Propionibacterium acnes* (*P. acnes*), which resides in the sebaceous glands beneath the skin. Researchers hypothesized that if the local microbiome is the source of surgical site infections, infections near the shoulder would show the marker organism *P. acnes* more often than infections after knee and hip surgeries that involve incisions over body surfaces not prevalent with *P. acnes.* *Id.* at 28.

The research established the link between *P. acnes* by revealing a significant number of infections after shoulder surgery, including prosthetic joint infections, caused by *P. acnes*. Because *P. acnes* is found in the sebaceous glands below the skin, it is not well controlled with skin preps. To address this, researchers also pre-surgically treated the patient with benzoyl peroxide (BPO), which penetrates the skin and kills *P. acnes* below the surface. They found that the BPO application significantly reduced pre-operative cultures. *Id.* at 29. The *P. acnes* research, as explained by Dr. Wenzel, supports the concept that local flora at the site of the incision harbor the bacteria that cause a large proportion of surgical site infections. *Id.* at 31. "The implication is that surgeons do their best to minimize the number of bacteria at the incision site, but it is never sterile but as clean as possible, given the microbiome and human activity in disturbing the microbiome." *Id.* at 31.

Dr. Wenzel also details the observational studies that offer corroborating support that the "airborne route of infection is not common in surgery" and that the patient's

microbiome is the source. *Id.* at 31. While scientists are still debating how organisms get to the wound site from the microbiome of the skin and nares, it is proven they do arrive there. As Dr. Wenzel concludes:

> An incontrovertible amount of data from the literature support the patient's own microbiome (flora of skin and nares) as key sources of bacteria causing SSIs. Studies show that control of the microbiome by improved pre-surgical skin preps and use of effective nasal decolonization substantially reduce the SSI rate.

Id. at 72.

During his deposition, Plaintiffs asked Dr. Wenzel whether various equipment in the operating room causes surgical site infections (*e.g.*, anesthesia machines, surgical lights, computer monitors, drop buckets, trash receptacles). Dr. Wenzel indicated he has not seen studies, data, or papers linking the equipment to a surgical site infection. Therefore, he agreed there was a low probability the equipment causes surgical site infections. DX2, Wenzel Depo. at 99:4-104:2. Dr. Wenzel did not agree, however, that the equipment presented possible causes of infection that could be "excluded." Nor is his testimony tantamount to an acknowledgement by Dr. Wenzel that only two possible causes of the Plaintiffs' PJIs exist (bacteria on the patient's skin *or* airborne bacteria stirred up by the Bair Hugger). Plaintiffs' Memorandum at 4, ECF No. 813 at 5. The fact that other equipment in the operating room has not been studied, and is believed to pose little risk, is of no consequence here where (i) scientific evidence establishes that the Bair Hugger system is not generally capable of causing surgical site infections; and (ii) volumes of scientific evidence link the bacteria on the patient's skin to surgical site infections.

In conclusion, Plaintiffs' attack on Dr. Wenzel's opinion that the bacteria on and in the patient are the most likely cause of surgical site infections is meritless. As detailed above, and in Dr. Wenzel's report, this opinion is neither speculative nor devoid of evidence. *See Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011) (Ericksen, J.) (finding that rebuttal experts' opinions were not unduly speculative because they "sufficiently applied their expertise to the facts and methodologies used by each of [plaintiff's] experts in forming their conclusions").

III. DR. WENZEL'S OPINIONS ABOUT COMORBIDITY AND INFECTION ARE RELEVANT.

As Dr. Wenzel explains in his report, infection is "a multifactorial event with several contributing aspects of the risk." DX1, Wenzel Report at 21. While bacteria are necessary to cause a PJI, they are not sufficient. DX2, Wenzel Depo. at 275:10-12. Dr. Wenzel succinctly summarized his opinion:

> It is important to point out the multifactorial components of infections. Bacteria are a necessary but not sufficient cause. Risk factors address the components that increase risk for some patients. So if no bacterium and no risk factor is sufficient to cause an infection, all are in part risk factors that combine to cause an infection in some patients. If the question is what caused the infection of Mr. Jones, one could point to his organism recovered, his diabetes and obesity and say that all contributed, all caused the infection.

DX1, Wenzel Report at 57.

Dr. Wenzel does not agree, as Plaintiffs contend, that causation for PJIs can be boiled down to either the bacteria on the patient's skin at the surgical site or airborne bacteria stirred up by the Bair Hugger system. (Memorandum, ECF No. 813 at 6.) Plaintiffs' position reflects an overly simplified and uninformed view of the complexities

of determining the source of any patient's surgical site infection. Contrary to Plaintiffs' assertion that the only "cause" of infections is bacteria, Dr. Wenzel explained how a patient's comorbidities are causal:

> Q. Okay. It is the bacteria that causes the infection, and it is the host that may be susceptible more or less than the average human and may allow the infections to progress.
>
> A. You and I are going to disagree. I mean, I think that risk factors are, by definition, causal, and – that's why I tried to give you the twins, one was a diabetic obese, and without that that person, the twin, didn't get an infection.

DX2, Wenzel Depo. at 276:8-18.

As an epidemiologist, Dr. Wenzel is qualified to assist the trier of fact in answering the central causation question in this case. And because there is no scientific method from which the cause of any Plaintiff's surgical site infection can actually be determined in these cases, it will assist the trier of fact to understand the known and likely causes of a patient's infection (of which the Bair Hugger system is not scientifically established to be one). As Dr. Wenzel explains, a patient's risk factors are part of the causal chain and address the question of why some patients develop surgical site infections after operation and others do not. *Id.* at 57. His report includes in-depth discussion of the research on how various risk factors (smoking, diabetes, obesity, age, COPD, heavy alcohol consumption, surgery at institutions with lower surgical volumes, timing of perioperative antibiotics, and history of prior joint replacement) increase a patient's likelihood of getting an infection. Dr. Wenzel also explains that while the

science of the microbiome is young, a number of studies show that the microbiome density changes with the comorbidities he addresses. *Id.* at 57.

> Risk factors thus play a role in SSIs by altering or increasing the bacterial burden in the microbiome and/or possibly by reducing the host's ability to resist her own microbiome or the bacteria from exogenous sources.

*Id.*at 57.

The trier of fact will be asked to determine what caused each Plaintiff's infection, including whether the Bair Hugger patient warming system caused it. Because Dr. Wenzel's testimony about risk factors and comorbidities relate directly to the question of causation, they are relevant and admissible.

IV. DR. WENZEL IS QUALIFIED TO RENDER OPINIONS ABOUT HYPOTHERMIA AND LAMINAR FLOW.

Finally, Dr. Wenzel is qualified to address hypothermia during surgery and topics addressing whether laminar flow reduces surgical site infections. Dr. Wenzel has addressed both of these topics within the framework of his expertise as an infectious diseases epidemiologist specializing in understanding the causes and treatment of hospital-acquired infections. DX2, Wenzel Depo. at 31:15-32:5; 142:25-143:10; 143:25-144:20. Plaintiffs do not challenge the relevancy of Dr. Wenzel's "hypothermia" and "laminar flow" positions, but only his qualifications.

Hypothermia. Dr. Wenzel is qualified to discuss the effects of anesthesia on a patient's core body temperature, and the benefits of patient warming. Specifically, he opines that preventing hypothermia during surgery – in particular, by using the Bair Hugger patient warming system – has many positive patient outcomes, including reduced

surgical site infections. Dr. Wenzel explains how he thoroughly reviewed the research on hypothermia and the incidence of surgical site infection, including the clinical trials (Kurz and Melling), meta-analyses (including AORN), and the eight Bair Hugger studies that looked for "anything the Bair Hugger may have done in terms of colony-forming units." DX2, Wenzel Depo.at 34:11-22. He then formulated his own opinions of that research using his background in infectious diseases and hospital-acquired infections. *Id.* at 31:15-32:5; 33:13-34:2. As a medical doctor with nearly 50 years of patient care experience and as a leading scholar in the field of infectious diseases, Dr. Wenzel is qualified to offer opinions related to the benefits of patient warming using the Bair Hugger system, especially with respect to the risk of infection. Accordingly, because Dr. Wenzel is well qualified to speak to the hypothermia-related opinions he offers, this aspect of the Plaintiffs' motion should also be denied.

Laminar flow. Dr. Wenzel's discussion of the research on laminar flow and surgical site infections relates to his specific opinion in this case that the Bair Hugger system *does not increase bacteria in the air at the surgical site*. Generally, Dr. Wenzel described laminar flow as the unidirectional (downward) filtered air flow system used in some operating rooms. *Id.* at 42:19-20. Laminar flow was implemented to reduce the numbers of bacteria in the operating room and was, in turn, believed to reduce surgical site infections. DX1, Wenzel Report at 38.

In a lengthy exchange during his deposition, Dr. Wenzel explained how his opinions relate to the research on laminar flow and surgical site infections. DX2, Wenzel Depo. at 39:24-42:7. Specifically, he looked at studies that question whether laminar

flow is a benefit (and implicitly, whether disruption of laminar flow is a detriment). Dr. Wenzel first analyzed data related to whether use of laminar flow and reduced numbers of bacteria in operating rooms reduces surgical site infection. He highlighted the three studies showing "a worse outcome with the use of laminar air flow," i.e., more surgical site infections with laminar flow. DX1, Wenzel Report at 38. His report then details the systematic review and meta-analysis of laminar flow and surgical site infections done by Peter Bischoff and colleagues, which concluded there is "no benefit for laminar flow vs. conventional turbulent air in total THA (hip) or TKA (knee) surgery." *Id.* at 39. Based, in part, on this research, Dr. Wenzel concluded that there is "no compelling data linking airborne organisms in the operating room to SSIs." DX1, Wenzel Report at 40.[8] In conjunction with his discussion of the scientific literature on laminar flow, Dr. Wenzel also analyzed whether there was any evidence that the Bair Hugger system would increase airborne bacteria. There is no such evidence, as detailed in Section I.A., *supra*. Dr. Wenzel is a researcher, editor, scholar, and clinician, and is qualified to review the research on whether laminar flow reduces surgical site infections and discuss how that research fits in to his opinion that the Bair Hugger system is not generally capable of causing PJIs. These opinions are admissible.

[8] Contrary to Plaintiffs' assertion, Dr. Wenzel did not concede his lack of expertise by testifying that he would "love to know more about laminar flow." DX2, Wenzel Depo. at 43:25-44:12. Instead, Dr. Wenzel explained that his opinion is based upon his review of studies involving over 300,000 patients (Brandt (99,230 patients) and Gastmeier (over 75,000 total knee arthroplasties and over 120,000 total hip arthroplasties), and Bischoff's recent meta-analysis. DX2, Wenzel Depo. at 43:25-44:12; DX1 Wenzel Report at 38-40.

V. DR. WENZEL'S OPINIONS ARE ALSO ADMISSIBLE UNDER MINNESOTA LAW.

Rule 702 of the Minnesota Rules of Evidence states that a qualified expert's opinions and testimony are admissible if they have both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000); *see also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming the district court's determination that the plaintiff's expert's general causation theory is not generally accepted). As detailed above, Dr. Wenzel's opinions are appropriately based upon his extensive professional experience as a medical doctor and scholar in the field of infectious diseases epidemiology. He relied on his vast experience and expertise in reviewing scientific literature across numerous interrelated topics. His conclusions are generally accepted in the scientific and medical communities (n.5, *supra*), and Dr. Wenzel's opinions are admissible in the Minnesota state cases.

CONCLUSION

Dr. Wenzel's expert testimony and opinions are admissible under Fed. R. Evid. 702 and Minn. R. Evid. 702. Dr. Wenzel opines that *the Bair Hugger system is not generally capable of causing a prosthetic joint infection*; rather, the most likely cause is the bacteria on and in the patient's own body. His testimony will assist the trier of fact in deciding the ultimate causation questions in this case, and Plaintiffs' motion should be denied.

Dated: October 3, 2017

Respectfully submitted,

s/Mary S. Young

Jerry W. Blackwell (MN #186867)
Mary S. Young (MN #0392781)
Benjamin W. Hulse (MN #0390952)
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
Phone: (612) 343-3248
Fax: (612) 343-3205
Email: blackwell@blackwellburke.com
myoung@blackwellburke.com
bhulse@blackwellburke.com

Bridget M. Ahmann (MN #016611x)
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
Phone: (612) 766-7000
Fax: (612) 766-1600
Email: bridget.ahmann@faegrebd.com

Counsel for Defendants 3M Company and Arizant Healthcare Inc.